



UNITED STATES DEPARTMENT OF COMMERCE  
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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/397,225	03/28/95	PERRICAUDET	N

18N2/0411

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EXAMINER

MILNE, A

ART UNIT PAPER NUMBER

1804

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DATE MAILED: 04/11/97

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☒ Responsive to communication(s) filed on 12-26-96
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-2, 6 and 9-35 is/are pending in the application.
- Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 13 and 33-35 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☒ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

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Claims 1-3, 6 and 9-35 are currently pending in U.S. Patent Application Number 08/397,225. The response and amendment filed 12-26-96 (paper #13) has been entered and carefully reviewed.

The rejection based upon 35 U.S.C. 112, first paragraph has been withdrawn in light of applicant's arguments filed 12-26-96.

Claims 2-3, 6, 9, 10, 12-18, 20-30, 32, and 34-35 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2-3, 6, 9, 10, 12-18, 20-30 and 32 are vague and indefinite because of the phrase "characterized". It is suggested that applicant's should use the term "wherein said.." and that the phrase "characterized in that the" should be deleted.

Claim 13 is vague and indefinite in that the Markush group contains various errors. More specifically, said Markush group contains both "neurotransmitters" and "precursors of neurotransmitters". These are art recognized terms; however, they are not proteins, they are known in the art to be chemical compounds and hence cannot be the products of gene transcription.

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Claim 13 is further vague and indefinite as it claims "blood derivatives", "synthetic enzymes", "trophic factors" and "genes encoding factors involved in coagulation". The specification fails to provide any definition and merely provides an identical list to what is being claimed. There is no disclosure of what these terms are to encompass and they are not art recognized terms; therefore, the disclosure remains vague and indefinite.

Claim 33 is vague and indefinite. It is not clear what is intended by the term "ORF 6/7" as such is not an art recognized term, nor is it described in the specification.

Claims 34 and 35 are vague and indefinite in the phrase "consisting essentially thereof". This applies to compositions wherein the composition has the constituents like cell media or cell populations and the phrase imparts the idea that there is more than one ingredient but that only one is important - i.e. that the others do not change its' properties.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 34 and 35 rejected under 35 U.S.C. § 102(b) as being anticipated by Berkner et al. or Bajocchi et al.

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The claims recite "all or part" of either the E2 or E4 gene regions of the adenovirus. Having "all or part" fails to render patentably distinct over the prior art which teaches adenoviruses with heterologous genes wherein said adenoviruses contain the E2 or E4 regions.

Berkner et al. disclose the use of adenoviral vectors. Berkner states on page 617, column 1 that the ability to dispense with 2-3 Kb in E4 Ad sequences would be advantageous in vector development. Berkner teaches on page 621, the use of recombinant adenoviral vectors, the ITR's and a packaging sequence. The reference clearly teaches how to make and use replication deficient adenoviral vectors which contain ITRs and all or part of the E2 or E4 gene regions. Therefore, the prior art anticipates the claimed invention.

Bajocchi et al. disclose replication deficient recombinant adenovirus vectors that contain a therapeutic DNA sequence, more specifically the gene coding for  $\alpha$ 1-antitrypsin. The reference teaches the use of type 5 adenovirus which contains all of the E2 and E4 regions. Therefore, the prior art anticipates the claimed invention.

Claims 1, 11, 19, 31 and 33 are considered allowable at this time for reasons of record.

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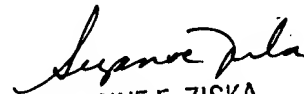
Any inquiry concerning this communication from the examiner should be directed to Andrew Milne, whose telephone number is (703) 308-4213. The examiner can normally be reached from 7:00 to 4:00 (Eastern Standard Time) Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jacqueline Stone, can be reached at (703) 308-3153. The fax number for art unit 1804 is (703) 308-4312.

Any inquiry of a general nature or relating to the status of the application should be directed to the group receptionist whose telephone number is (703) 308-0196.

Andrew Milne

  
3-31-97

  
SUZANNE E. ZISKA  
PRIMARY EXAMINER  
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